<u>REMARKS</u>

Applicants request reconsideration of the above-identified application in light of the amendments and remarks described herein. Claims 25-27 have been canceled, and Claims 1, 8-11, 13, 22, and 24 have been amended. Thus, Claims 1-24 are pending in this application.

Claims 1-15 and 21-24 have been rejected. Specifically, Claims 1-6, 8-10, 13-15, 22, 23, and 24, have been rejected under 35 U.S.C. § 102(b), and Claims 7, 11, and 12 have been rejected under 35 U.S.C. § 103(a). Claims 16-21 have been allowed. Applicants thank the Examiner for this notice of allowed subject matter. Applicants respectfully submit that all claims are now in condition for allowance. Accordingly, applicants request reconsideration and allowance of all claims.

Claim Rejections Under 35 U.S.C. § 102(b) As Anticipated By Orsak

Claims 1-6, 13-15, 22, 23 and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,162,223, issued to Orsak et al. (hereinafter "Orsak"). Applicants respectfully disagree. The following analysis focuses on independent Claims 1, 13, 22, and 24.

Orsak purportedly describes a joint fixation apparatus 10 having a rod 14 with discrete proximal and distal rod sections 15 and 16 held together by a flexible spring module connector member 19. At respective rod sections 15 and 16, clamps 28 and 29 form respective interfaces between bone pins 17 and 18 and discrete rod sections 15 and 16. Referring to FIGURE 3 of Orsak, the flexible spring module connector member 19 has a central spring section 22 and a center bore 23 that receives the discrete rod sections 15 and 16. The flexible spring module connector member 19 is designed and configured to flex, extend, and angulate, as seen in FIGURES 1, 6, and 15. Referring to FIGURES 19 and 20, the apparatus may include a flexible cable 75A or flexible rod 75B, in lieu of the multi-sectioned rod 14 shown in FIGURES 1-14.

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Claim 1 recites a fixation device for treating bone fractures, including an integral elongate fixator body having a length, a first support pin having a proximal end and a distal end, the distal end for coupling to a first bone segment and the proximal end movably coupled to the elongate fixator body, and a second support pin having a proximal end and a distal end, the distal end for coupling to a second bone segment and the proximal end movably coupled to the elongate fixator body. The proximal ends of the first and second support pins are movably

coupled to the elongate fixator body at selectively adjustable locations so as to define a first separation distance therebetween, and the support pins are moveable with respect to the elongate

separation distance increbetween, and the support phis are moveable with respect to the ciongate

fixator body by an applied external force to define a second separation distance therebetween.

Claim 13 recites a fixation device, including an integral support member, a plurality of support shafts movably associated with the support member, and at least one biasing component positioned between the support shafts by the support member. The biasing component and the support member movably interconnect the support shafts at a variable separation distance so as to provide controlled interaction between the support shafts upon application of a sufficient force on one of the shafts.

Claim 22 recites a fixation device used to treat bone fractures, including a support member having a longitudinal axis, and at least two support shafts having distal ends adapted to be connected to bone segments. The support shafts are slidably coupled to the support member in a spaced-apart manner, and the support shafts are oriented substantially transverse to the longitudinal axis of the support member. The support shafts are biased inwardly along the longitudinal axis of the support member at selectively adjustable locations so as to define a first separation distance therebetween, and wherein the support shafts are moveable with respect to the support member by an applied external force to define a second separation distance therebetween.

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Claim 24 recites a fixation device used to treat bone fractures, including an integral fixator body having a longitudinal axis, and first and second support pins each having distal ends adapted to be connected to a bone segment. The device further includes means for dynamically coupling the support pins to the fixator body in a selectively adjustable manner and for

controlling the movement of the first support pin with respect to the second support pin.

As is well known, a single prior art reference must disclose each and every element of a

claimed invention for the claim to be fully anticipated.

Applicants respectfully submit that Orsak fails to teach or suggest each and every element of independent Claims 1, 13, 22, and 24. Specifically, Orsak fails to teach or suggest "an integral elongate fixator body having a length...wherein the proximal ends of the first and second support pins are movably coupled to the integral elongate fixator body at selectively adjustable locations so as to define a first separation distance therebetween, and wherein the support pins are moveable with respect to the fixator body by an applied external force to define

a second separation distance therebetween," as recited in amended Claim 1.

In addition, Orsak fails to teach or suggest "an integral support member...wherein the biasing component and the support member movably interconnect the support shafts at a variable separation distance so as to provide controlled interaction between the support shafts upon

application of a sufficient force on one of the shafts," as recited in amended Claim 13.

Moreover, Orsak fails to teach or suggest "an integral support member having a longitudinal axis...and at least two support shafts having distal ends adapted to be connected to bone segments, the support shafts being slidably coupled to the support member in a spaced-apart manner...wherein the support shafts are biased inwardly along the longitudinal axis of the support member at selectively adjustable locations so as to define a first separation distance therebetween, and wherein the support pins are moveable with respect to the fixator body by an

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Seattle, Washington 98101 206.682.8100 applied external force to define a second separation distance therebetween," as recited in amended Claim 22.

Finally, Orsak fails to teach or suggest "an integral fixator body...and means for dynamically coupling the [first and second] support pins to the fixator body in a selectively adjustable manner and for controlling the movement of the first support pin with respect to the second support pin," as recited in amended Claim 24.

In contrast, Orsak teaches that clamps 28 and 29 form respective interfaces between bone pins 17 and 18 and discrete rod sections 15 and 16. In this regard, the clamps 28 and 29 are fixedly coupled to the discrete rod sections 15 and 16. Orsak does not teach a "movable" or "dynamic" connection between the clamps 28 and 29 and an integral rod when an external force is applied to the joint fixation apparatus 10 that could result in a variable separation distance between the two clamps 28 and 29. Rather, the clamps 28 and 29, once set, are fixed to their respective rod sections 15 and 16 and move with the respective rod sections 15 and 16.

Even if the discrete rod sections 15 and 16 of Orsak are replaced with a flexible cable 75A or flexible rod 75B (see FIGURES 19 or 20), Orsak still fails to teach or suggest each and every element of independent Claims 1, 13, 22, and 24. In this construction, Orsak still does not teach a "movable" or "dynamic" connection between the clamps 28 and 29 and the flexible cable or flexible rod 75A or 75B when an external force is applied to the joint fixation apparatus 10. Rather, the clamps 28 and 29, once set, are fixed to the flexible cable or flexible rod 75A or 75B and thus move with the flexible cable or flexible rod 75A or 75B. Accordingly, applicants respectfully request withdrawal of the rejections to these claims.

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Claim Rejections Under 35 U.S.C. § 102(b) As Anticipated By Luque

Claims 8-10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent

No. 4,790,297, issued to Luque (hereinafter "Luque"). Applicants respectfully disagree. The

following analysis focuses on independent Claim 8.

Luque purportedly describes a spinal fixation system 11 having a plate 13 with a slot 23

and a plurality of screws 15 extending through slot 23. The system 11 further includes a plate

ring 41 "for encircling the plate 13 to prevent the plate 13 from spreading when the screws 15 are

snugged [sic] down" (see Col. 4, lines 1-4). The system also may include fixation means 47,

such as a body 49 and a lock screw 51, for selectively fixedly securing a screw 15 relative to the

plate 13.

Claim 8, as currently amended, recites a bone fracture fixation kit, including an elongate

fixator body having a length and a slot disposed substantially along the length, a first support

shaft having a distal end for coupling to a first bone segment of a user and a proximal end for

being slidably received within the slot of the elongate fixator body, and a second support shaft

having a distal end for coupling to a second bone segment and a proximal end for being coupled

to the elongate fixator body. The bone fracture fixation kit further includes a biasing component

having an inner passage for receiving the elongate fixator body at least partially therein, wherein

the biasing component is adapted to be received by the elongate body and be disposed between

the first and second support shafts when the first and second support shafts are received by the

slot of the elongate fixator body to provide a selected separation therebetween.

Applicants respectfully submit that Luque fails to teach or suggest each and every

element of independent Claim 8, as currently amended. Specifically, Luque fails to teach or

suggest "a biasing component having an inner passage for receiving the elongate fixator body at

least partially therein, wherein the biasing component is adapted to be received by the elongate

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body and be disposed between the first and second support shafts when the first and second

support shafts are received by the slot of the elongate fixator body to provide a selected

separation therebetween," as recited in amended Claim 8.

In contrast to the claimed invention, Luque merely teaches a plate ring 41 that slides over

plate 13 to prevent plate 13 from spreading when the screws are tightened down. The Luque

plate ring 41 is not a biasing member. Accordingly, applicants respectfully request withdrawal

of the rejections to Claim 8, and Claims 9 and 10 depending therefrom.

Claim Rejections Under 35 U.S.C. § 103(a)

Claim 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Orsak. In

addition, Claims 11 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over

Luque. Applicants respectfully disagree.

To establish a case of obviousness, the prior art references must teach or suggest all of

the claim limitations; there must be some suggestion or motivation, either in the references or in

the knowledge of one skilled in the art, to modify the reference or to combine the reference

teachings; and there must be a reasonable expectation of success.

For at least the same reasons as discussed above with regard to the rejections under 35

U.S.C. § 102(b), applicants respectfully submit that dependent Claims 7, 11, and 12 are also

allowable over the cited references, whether cited alone or in any combination. Accordingly,

applicants respectfully request withdrawal of the rejections to these claims.

Allowed Claims

Again, Applicants thank the Examiner for the notice of allowed Claims 16-21.

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CONCLUSION

In view of the foregoing amendments and remarks, applicants respectfully submit that the present application is in condition for allowance. The Examiner is invited to contact the undersigned with any remaining questions or concerns.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first-class mail with postage thereon fully prepaid and addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the below date.

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